REMARKS

In the Action, the Office indicates that the amendments to the Remarks are illegible and are not easily perceived. Applicants respectfully submit that all Remarks are clear as previously presented and are re-submitting the previously submitted response by mail rather than facsimile to prevent any possible transmission problems.

Claims 1-56 are pending. Claims 30, 36, and 50 are amended herein. Applicant submits that the amendments introduce no new matter. Support for the amendments can be found throughout the application as originally-filed and in the drawings (e.g. see page 15, line 27 – page 16, line 16).

Applicant makes these claim amendments and cancellations without prejudice. Also, applicant disagrees with all rejections and makes these claim changes only to expedite prosecution and move to allowance as soon as possible.

1. 35 U.S.C. §112 Rejections

Claims 30 and 31 are rejected under 35 U.S.C. §112, first paragraph. Applicants amend claim 30 herein to clarify that the delivery mechanism includes the valve (as set forth, e.g. at page 15, line 27 – page 16, line 16). Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 36, and 37 are rejected under 35 U.S.C. §112, second paragraph. Applicants amend claim 36 to correct a typographical error such that claim 36 properly depends from claim 35 rather than claim 30. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. §102 Rejections

Claims 1-9, 11, 18-29, 35, and 38-56 are rejected under 35 U.S.C. §102(e) in view of Berke (US 6,336,917).

Applicants respectfully traverse.

Applicants' independent claim 1 recites a device for the delivery of a substance to the eye comprising a housing for holding the substance, at least one outlet port through which the substance is delivered from the device to the eye, and a non-aerosol, non-electric delivery mechanism, whereby the substance is delivered to the eye in the form of a spray or mist.

Applicants' independent claim 49 recites a method for the delivery of a substance to the ocular surface of a patient comprising providing a non-aerosol, non-electric delivery device housing the substance, positioning the patient's head such that the line of sight is in a generally horizontal direction, positioning device in front of the eye in the line of sight, and delivering the substance to the eye as a spray or mist in a generally horizontal direction.

Applicants' independent claim 50 recites method to minimize risk of infection when a substance is delivered to the eye comprising providing a non-aerosol, non-electric delivery device housing the substance, holding the device a distance away from the eye without contacting the eye, and delivering the substance to the eye in the form of a spray or mist.

Berke describes an ocular inspection and treatment apparatus comprising an inner 20 and outer housing 30. The inner housing 20 contacts the eyelid and surrounding eyeball. The outer housing 30 contacts the skin over the bony orbit surrounding the eye. (see col. 4, lines 56-67) The apparatus can be used, as such, to view the eye. The apparatus can further include a medicine dispenser 50 that receives a vial 60 of medicine so that the apparatus can be used to administer medicine to the eye (col. 6, lines 5-14). As shown in the figures and described in the specification, the vial 60 is positioned within the device in an upright position with a nozzle 62 extending downwards from the vial 60. Medicine within the vial 60 is delivered by applying downward pressure on the vial 60 to depress nozzle 62. This releases a metered amount of medicine from the vial 60. This is a conventional metered dose dispenser, such as those commonly used to deliver medicaments to the lungs of individuals with respiratory problems such as asthma. These metered dose dispensers utilizes a pressurized container of aerosol in

which a medicine is dispersed. By depressing the nozzle 62, an atomizing valve is opened to thereby release a mist or puff of the medicine/propellant mixture.

Applicants respectfully submit that Burke at least fails to teach or suggest a device for the delivery of a substance to the eye comprising a housing for holding the substance and a non-aerosol, non-electric delivery mechanism, whereby the substance is delivered to the eye in the form of a spray or mist, as recited in Applicants' claim 1.

Applicants further submit that Berke at least fails to teach or suggest a method for the delivery of a substance to the ocular surface of a patient comprising providing a non-aerosol, non-electric delivery device housing the substance, and delivering the substance to the eye as a spray or mist in a generally horizontal direction, as recited in Applicants' claim 49.

Applicants further submit that Berke at least fails to teach or suggest a method to minimize risk of infection when a substance is delivered to the eye comprising providing a non-aerosol, non-electric delivery device housing the substance and delivering the substance to the eye in the form of a spray or mist, as recited in Applicants ' claim 50.

Berke's device, as shown in the figures and described necessarily utilizes an aerosol or an electric delivery mechanism to deliver the substance in the vial 60 downward through nozzle 62 and out of the device in the form of a spray or mist. Given the design of Berke's device and its positioning during use, there could be no other mechanism by which the contents of the vial 60 could be delivered in the form of a spray or mist other than by use of an aerosol under pressure.

Still further, with respect to claim 50, Applicants recite a method to minimize risk of infection when a substance is delivered to the eye wherein the device is held a distance away from the eye without contacting the eye, and delivering the substance to the eye in the form of a spray or mist. According to Berke, the device is specifically designed such that the inner housing 20 contacts the eyelid and surrounding eyeball, while the outer housing 30 contacts the

skin over the bony orbit surrounding the eye (see col. 4, lines 56-67). Thus, Berke does not teach a method wherein the device is held a distance away from the eye without contacting the eye. Rather, Berke is specifically designed for such contact so that the eye can be viewed and treated as specifically set forth by Berke. Further, Applicants respectfully submits that this method and contact described by Berke would, in fact, increase the risk of infection.

Thus, Applicants respectfully submit that claims 1, 49, and 50 are not anticipated by Berke. Claims 2-48, and 51-56 depend from claim 1 and, likewise, are not anticipated by Berke. Reconsideration and withdrawal of the rejection is respectfully requested.

3. 35 U.S.C. §103 Rejections

Claims 10, 12-17 are rejected under 35 U.S.C. §103(a) in view of Berke (US 6,336,917).

Applicants respectfully traverse.

As set forth above, Berke's device, as shown in the figures and described necessarily utilizes an aerosol or an electric delivery mechanism to deliver the substance in the vial 60 downward through nozzle 62 and out of the device in the form of a spray or mist. As such, Berke at least fails to teach or suggest Applicants' claim 1.

Accordingly claim 1 is patentable over Berke. Claims 10, 12-17 depend from claim 1 and, likewise, are patentable over Berke. Reconsideration and withdrawal of the rejection is respectfully requested.

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CONCLUSION

In view of the foregoing, applicant respectfully requests reconsideration, withdrawal of all grounds of rejection and objection, and allowance of claims 1-56 in due course. The Examiner is invited to contact applicant's undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,

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